
CANNABIS: A COMMONWEALTH MEDICINAL PLANT, LONG SUPPRESSED, NOW AT RISK OF MONOPOLIZATION

SUNIL AGGARWAL[†]

INTRODUCTION

The acknowledgement that cannabis is a medicinal plant has yet to be made by federal drug regulators. However, in July 2010, the Department of Veterans Affairs, a federal agency, adopted a policy that will formally allow patients treated at its hospitals and clinics to use medical marijuana in the states where it is legal.¹ Additionally, in October 2009, another federal agency, the United States Department of Justice (DOJ), announced that, as a matter of priority, it would endeavor not to target or prosecute those who are using and distributing cannabis in "clear and unambiguous compliance" with state medical-marijuana laws.² While both of these policies are fraught with loopholes allowing subjective interpretation, and while they create no new legal rights nor grant any medical patient or provider full legal license to produce, provide, or consume cannabis or other botanical cannabinoid-based medicines, they are landmark steps forward for a federal government that for decades has, as a matter of policy, vehemently denied the fact that cannabis has any redeeming qualities whatsoever and treated it as nothing but highly dangerous, deserving of the strictest prohibition both nationally and globally.

THE ABSURDITIES OF THE PAST AND PRESENT

This pattern of the federal government's promotion of prohibition at all costs began in 1937 with the Congressional deliberations leading to the first de facto prohibitory federal law, the "Marihuana Tax Act." The Congressional Record from those hearings is rife with lurid tales of homicidal mania, racial slurs, and fears of miscegenation, each designed to enhance the threat level of marijuana use in civil society.³ The sole voice of cautious reason was the American Medical Association (AMA), whose representative undercut the distortions by insisting on referring to

[†] MD, PhD, Resident Physician, Virginia Mason Medical Center and NYU School of Medicine.

1. See Dan Frosch, *V.A. Eases Rules for Users of Medical Marijuana*, N.Y. TIMES, July 23, 2010, available at <http://www.nytimes.com/2010/07/24/health/policy/24veterans.html>. Currently, fourteen states and the District of Columbia permit the use of medical marijuana.

2. See David Stout & Solomon Moore, *U.S. Won't Prosecute in States That Allow Medical Marijuana*, N.Y. TIMES, Oct. 19, 2009, available at http://www.nytimes.com/2009/10/20/us/20cannabis.html?_r=1&scp=62&sq=&st=nyt.

3. See *Taxation of Marihuana: Hearing on H.R. 6385 Before the H. Comm. On Ways & Means*, 75th Cong. (1937).

the drug strictly by its scientific name, “cannabis.” The AMA stood virtually alone in their opposition to the bill on the grounds that cannabis was not inherently dangerous, had already been part of the United States Pharmacopoeia for nearly a century, and had irreplaceable,⁴ already-accepted and future-promising medical utilities that would go unrealized should the bill become law. However, their position was publicly falsified on the Congressional floor just before a vote was taken in favor of the law’s passage.⁵ The act was soon after signed into law on August 2, 1937. The federal government’s expert marijuana witness was Dr. James C. Munch, a pharmacologist from Temple University. He testified to Congress during the hearings that his experiments in dogs had shown that an animal’s personality would “disintegrate” after use of the drug for three months. In later years, Munch continued to serve in his official capacity as an expert witness in marijuana-related homicide trials in which defendants successfully claimed that merely being in the presence of marijuana caused them to be overcome by murderous rage. At two capital trials in 1938, Munch testified that, in the course of his research, he had self-experimented with marijuana, and while under its spell for fifteen minutes, he believed that he had transformed into a bat, flown around the world, and eventually landed head-down in a vat of ink, staying there for 200 years.⁶ These fantastical claims were sworn statements of the federal government’s official scientific expert witness on marijuana. Moreover, any attempts to make accurate scientific statements about the effects of marijuana in humans based on empirical study, such as the La Guardia Committee Report issued by the New York Academy of Medicine in 1944, were either ignored or actively suppressed by the federal government in the ensuing years.

The modern era is no less absurd. In 1970, when Congress was drafting the so-called “Comprehensive Drug Abuse Prevention and Control Act”⁷ in the wake of the Supreme Court’s decision to strike down the Marihuana Tax Act the year prior, it sought input on the appropriate initial regulatory classification of cannabis from Dr. Roger O. Egeberg. From 1969-1971, Dr. Egeberg, former personal physician to General Douglas MacArthur, was Assistant Secretary of Health in the United States Department of Health and Human Services (DHHS),⁸ the agency under which the Food and Drug Administration (FDA) is housed. As

4. *Taxation of Marihuana: Hearing on H.R. 6385 Before the H. Comm. On Ways & Means, 75th Cong. (1937)* (statement of William C. Woodward, Legislative Counsel, American Medical Association). In addition to its analgesic and antispasmodic properties, Woodward testified that “Cannabis or Indian hemp” had a unique and unparalleled utility in psychotherapy “to revive old memories, and psychoanalysis depends on revivification of hidden memories.” *Id.*

5. MARTIN BOOTH, *OPIUM: A HISTORY* 188 (2003).

6. See LARRY SLOMAN, *REEFER MADNESS: THE HISTORY OF MARIJUANA IN AMERICA* 111-13 (St. Martin’s Griffin 1998) (1979).

7. More specifically, the Controlled Substances Act (CSA).

8. Then called the Department of Health, Education and Welfare.

documented in the CSA's legislative history, his testimony instructed Congress that:

Since there is still a considerable void in our knowledge of the plant and effects of the active drug contained in it, our recommendation is that marihuana be retained within schedule I at least until the completion of certain studies now underway to resolve the issue. If those studies make it appropriate for the Attorney General to change the placement of marihuana to a different schedule, he may do so in accordance with the authority provided under section 201 of the bill.⁹

The problem with this methodology, however, is that while the Attorney General may choose "to change the placement of marijuana to a different schedule" in accord with the results of the above-referenced "studies now underway," and other such studies, he/she has simply chosen not to do so. In other words, "he may do so" also allows the possibility that he may not do so. This is inappropriate, unscientific, and not in line with the intent of the process duly outlined. Nevertheless, this is what has transpired.

"Certain studies now underway" referred to the comprehensive report being written at that time by the "National Commission on Marihuana and Drug Abuse" whose tasks were enumerated by Congress when the CSA was adopted on October 27th, 1970, and under whose aegis numerous scientific investigations were undertaken and prior ongoing studies incorporated. Congress clearly stated that with regards to "the appropriate location of marihuana within the schedules of the bill . . . the recommendations of this Commission will be of aid in determining the appropriate disposition of this question in the future."¹⁰ Seventeen months later, on March 22nd, 1972, the Commission issued a report entitled "Marihuana: A Signal of Misunderstanding." Six months prior, when word began to leak that Commission would reject total prohibition and instead recommend a federal policy of "partial prohibition" in which cannabis would be publicly contraband but legally allowed by adults to be possessed, consumed, and cultivated in private or transferred between adults for small or insignificant remuneration, President Nixon became furious because he associated the drug with groups in society he despised: Jews, psychiatrists, war protestors, and communists.¹¹ As documented on declassified tape recordings from the White House Oval Office on September 9th, 1971, he told his appointed Commission chair, former Pennsylvania Governor Raymond Shafer, that the Commission

9. Letter from Doctor Roger Olaf Egelberg, Assistant Sec'y of Health in the Dep't of Health, Educ. and Welfare, to Harley O. Staggers, Chairman of the House Committee on Interstate and Foreign Commerce, Aug. 14 1970.

10. *Id.*

11. See <http://www.csdp.org/research/nixonpot.txt>.

had better not come out with a report that was “soft on marijuana.” Strategizing for political expediency over factual review, Nixon opined: “I think there’s a need to come out with a report that is totally, uh, uh, oblivious to some obvious, uh, differences between marijuana and other drugs, other dangerous drugs. . . .” Nixon further warned Shafer: “Keep your Commission in line.”¹²

DUE PROCESS DENIED

Undeterred, the Commission recommended a legal reclassification of cannabis away from a category of absolute dangerousness. In considering the classification of cannabis under international treaty—the Single Convention, wherein, thanks to U.S. pressure in the prior decade, cannabis was relegated to the most prohibited class of “narcotics,” Schedule IV (reversed numerical ordering from the U.S. scheme),¹³ the Commission found that while cannabis:

[H]ad no recognized medical uses at this time [it] does not render its users physically dependent, and is not as incapacitating as other substances in the Single Convention. . . . The inclusion of cannabis in Schedule IV of the Single Convention which equates it with heroin is inappropriate. . . . Therefore, the Commission suggests that the United States adopt the position that the existing status of marihuana under the Single Convention is not appropriate. . . and [seek instead] for diminished controls of cannabis.¹⁴

Yet, contrary to this recommendation, cannabis was retained in the most restrictive classification under international law and continues to be classified, with heroin, in the most dangerous drug classification in the United States, Schedule I. To recap, in 1970, Congress asked the DHHS in which Schedule to place cannabis in the CSA; the DHHS representative told Congress to temporarily retain cannabis in Schedule I pending study, which it did. In 1972, the study concluded that it was inappropri-

12. *Id.*

13. Schedule IV was reserved for substances “for which deletion from general medical practice is desirable because of the risk to public health.” United Nations Single Convention on Narcotic Drugs, Mar. 30, 1961, 520 U.N.T.S. 151. This classification for cannabis, championed by the U.S., was opposed by a number of countries at the U.N. Economic and Social Counsel Plenipotentiary Conference of 73 countries held in New York City from 24 January to 25 March 1961. For example, the delegate representing the Indian government stated that “India would not be able . . . to enforce prohibitions on the use of those substances [ganja and bhang], particularly in remote localities where, as inexpensive sedatives, they were used for medical and quasi-medical purposes” and opposed its placement in Schedule IV with heroin. U.N. Conference for the Adoption of a Single Convention on Narcotic Drugs, 13th Plenary Meeting, 59 U.N. Doc. U.N. E/CONF. 34/24 (Feb. 8, 1961). While all representatives generally agreed that cannabis ought to be generally prohibited in principle, those from countries such as Ghana, Pakistan, France, United Kingdom, Germany, Uruguay, and Burma verbally supported the Indian concerns and mostly wished to see cannabis treated like opium, for indigenous and traditional uses to be tolerated, and for future medical applications to not be foreclosed. U.N. Conference for the Adoption of a Single Convention on Narcotic Drugs, 13th Plenary Meeting, 59-62, U.N. Doc. U.N. E/CONF. 34/24 (Feb. 8, 1961).

14. NAT’L COMM’N ON MARIHUANA AND DRUG ABUSE, MARIHUANA: A SIGNAL OF MISUNDERSTANDING 545-46 (1972).

ate to classify cannabis with heroin and that it ought to be placed into a less restrictive category in which, at the very least, private consumption by adults would be legally allowed; the Nixon Administration balked and refused to take the appropriate action. To this day, the federally commissioned panel's recommendation to reclassify cannabis has never been implemented by any branch of the federal government. Marijuana is still classified, with heroin, as a Schedule I drug. This means that, by law, it is defined as having a lack of accepted safety for use under medical supervision, a high potential for abuse, and no currently accepted medical use in treatment in the United States.

Over the past three decades, the government has continued with this pattern of good faith, due process denials in matters pertaining to cannabis. A cannabis rescheduling petition, filed by citizens in 1972, was delayed from being heard for over a decade. Finally, after a hearing on the petition in 1985, a Drug Enforcement Administration (DEA)¹⁵ Administrative Law Judge (ALJ) ruled that, based on the available evidence, cannabis should be rescheduled to Schedule II, with painkillers and anesthetics such as morphine and cocaine, and that to not do so would be “unreasonable, arbitrary, and capricious.”¹⁶ The DEA rejected their own judge's ruling and, in 1994, a federal court denied the petitioners' appeal. In 2007, another DEA ALJ ruled that it would be in the public's interest to have more than one licensed facility to produce research-grade cannabis, and that a certain Plant and Soil Sciences Professor applicant should be granted such a license.¹⁷ This ruling, too, was rejected by the DEA in 2009, leaving cannabis clinical studies to continue to be approved and conducted at a snail's pace with substandard-quality material produced by a monopoly, and only after potential investigators have waded through tremendous red tape.

NEW DEVELOPMENTS ON AN OLD MEDICINE

In recent years, with increased understanding of the chemistry and pharmacology of cannabis and the fascinating endogenous cannabinoid signaling system with which it interacts, new rescheduling petitions have been filed¹⁸ and new respected voices have emerged in the public discussion about the appropriate classification of cannabis—major national medical societies, academies, and state pharmacy boards. After a year-long study, in 2009, the AMA reversed their previous position that cannabis be retained in Schedule I and “urge[d]” regulatory authorities to review its Schedule I classification¹⁹ so that the emerging field of can-

15. The DEA is part of the DOJ.

16. See <http://www.druglibrary.org/olsen/medical/young/young2.html>.

17. See <http://www.maps.org/ALJfindings.PDF>.

18. See http://www.drugscience.org/petition_intro.html.

19. A Schedule I classification is an ongoing, serious roadblock for U.S.-based researchers.

nabinoid medical science and development can take flight.²⁰ In a report recommending the policy change, entitled “Use of Cannabis for Medicinal Purposes” and written by the AMA’s premier study council,²¹ it was acknowledged that smoked cannabis from the federal supply has been shown to have bona fide medical utilities, citing as evidence well-controlled clinical trials that unequivocally demonstrated its ability to relieve neuropathic pain, stimulate appetite, and reduce spasticity in actual patients.²² This turnaround by the AMA came one and a half years after the American College of Physicians (ACP), the second largest physicians group in the country, arrived at a similar position and issued a report with even stronger language. Specifically, the ACP’s Report called for an evidence-based review by federal regulatory authorities on cannabis’s safety and efficacy and argued that to do so would “likely provide evidence to support both appropriate reclassification [of cannabis] and adjustment of federal drug enforcement laws, reduce conflict between federal and state law, and strengthen public confidence in the federal regulatory structure.”²³ These developments from mainstream professional medical societies came a full decade after the Congressionally-commissioned medical expert body, the Institute of Medicine, issued a government-requested report in 1999 that recommended that physicians be permitted to use cannabis in their medical practice for symptom relief in seriously ill patients in locally-implemented, peer-reviewed empiric treatment trials.²⁴ Developments in 2010 include the acknowledgment of cannabis’ medical utility by both the Iowa²⁵ and Oregon²⁶ Boards of Pharmacy, who both voted for down-scheduling of cannabis at their respective state levels.

Contrary to the claims of the federal government’s Office of National Drug Control Policy (ONDCP) and its supporters, the former being bound by federal law to take such actions as necessary to oppose any attempts to change the status of any Schedule I drug and to consider medical use of such substances only if they are passed through the FDA approval process,²⁷ rescheduling cannabis, in fact, does *not* require a drug manufacturer winning FDA approval of a specific claim of safety and efficacy for cannabis. Under the current legal framework of administrative law, while the United States Secretary for Health and Human Services can initiate a review of a drug’s Schedule, it is the Attorney

20. See <http://www.ama-assn.org/amednews/2009/11/23/prse1123.htm>.

21. The Council on Science and Public Health (CSAPH).

22. See

http://www.oregon.gov/Pharmacy/Imports/Marijuana/Public/AMAReport_CouncilSciencePublicHealth.pdf?ga=t.

pdf?ga=t.

23. See http://www.acponline.org/advocacy/where_we_stand/other_issues/medmarijuana.pdf.

24. See http://www.nap.edu/openbook.php?record_id=6376&page=7.

25. See http://www.state.ia.us/ibpe/pdf/2010_02_17minutes.pdf.

26. See <http://www.pharmacy.state.or.us/Pharmacy/Marijuana-Rescheduling.shtml>.

27. See <http://www.whitehousedrugpolicy.gov/about/98reauthorization.html>.

General, a political appointee who serves at the pleasure of the President, who is invested with the authority to change the Scheduling of a drug.²⁸ The CSA was written to allow the Attorney General the flexibility to move substances from one Schedule to another, depending on the needs of the social context or emerging scientific understanding. While it is true that rescheduling cannabis to—hypothetically—a Schedule II status would not allow it to be mass marketed, as it may be viewed as an FDA-unapproved botanical drug substance, it would allow for larger clinical studies to be more easily conducted and for its prescription to patients in locally implemented, empiric treatment trials because a pharmacy stocking system would be in place to carry and compound it. This is exactly how raw opium, a Schedule II botanical drug substance, is prescribed and dispensed in hospitals across the country, generally in the form of an FDA-unapproved tincture to treat refractory diarrhea. Since cannabis and cannabis preparations were part of the official United States Pharmacopoeia for nearly a century prior to the creation of the FDA and regulated under the Food and Drugs Act of 1906, they should be grandfathered for approval under the 1938 grandfather clause.²⁹ Furthermore, the historical farce that cannabis is somehow a “new drug” that appeared after June 30, 1938, should be ended.

PHARMACEUTICAL PRIVILEGE

In what has become a stain on participatory democratic decision-making based on sound science and expert review, none of the aforementioned recommendations by scientific and medical expert bodies have been implemented by United States federal administrators. Rather, they continue to treat cannabis as a political football instead of a medicinal plant that requires respectful, science-based regulation. This characterization continues to be true under the Obama Administration, despite a Presidential directive issued in March 2009 to federal agencies intended to guarantee scientific integrity in federal policymaking.³⁰

However, as had been predicted by some,³¹ what is making progress in this federal regulatory environment of cannabis prohibition sustained by a long-standing due process vacuum are private, multinational pharmaceutical interests wishing to capitalize on the clear medicinal value of cannabis by seeking to bring to market cannabis-based medicines with FDA-approved claims of safety and efficacy. For reasons of constructed scarcity, such a business model would stand to gain enormously by the maintenance of a regime of strict cannabis prohibition for the general

28. Notably, the DEA Chief Administrator generally acts as the Attorney General’s designee.

29. See 21 U.S.C. § 321(p)(1) (2006).

30. See http://www.whitehouse.gov/the_press_office/Memorandum-for-the-Heads-of-Executive-Departments-and-Agencies-3-9-09/.

31. Lester Grinspoon, *On the Pharmaceuticalization of Marijuana*, 12 INT’L J. OF DRUG POL’Y 377, 377-83 (2001), available at <http://www.rxmarijuana.com/Pharmaceuticalization.htm>.

public, effectively eliminating locally produced, legitimate competition. While there are numerous case studies in this area, including the DEA's recent allowance of Schedule III THC pills to be manufactured as natural product extractions directly from the federal cannabis farm, let us consider the lead pharmaceutical company in this field, British-based GW Pharmaceuticals. GW Pharmaceuticals was founded in 1998 by Dr. Geoffrey W. Guy, a physician and pharmaceutical developer, who had previously testified in a Parliament-level inquiry on cannabis's medicinal potentials. GW's industrial pursuits have done much to add to the understanding of cannabinoid medical science, but their ultimate goal is to bring to the lucrative consumer market highly characterized, FDA-approved, hash oil—mysteriously renamed nabiximols—to treat cancer pain. Privileged with exclusive, nationally granted access to cannabis germplasms (plant genetic resources) that GW may farm and harvest unmolested at undisclosed locations in the southern English countryside, bolstered by process patents issued for cannabis extraction methods first developed in the 19th century, and, most insidiously, camouflaged by a WHO-sanctioned nonproprietary drug naming sleight-of-hand which, in Orwellian fashion, distances liquid carbon dioxide cannabis extractions from the actual contraband plant matter from which they are derived, the company is making significant headway with US and international drug regulators. In late June 2010, twelve years after the company first imported cannabis seeds from European collections, GW announced full regulatory approval from British drug officials for a cannabis extraction for the treatment of spasticity in multiple sclerosis, a key milestone for the UK-based company.³²

In the U.S., GW insists that their lead product, once it completes the necessary number of clinical trials and wins FDA approval for the indication of cancer pain refractory to opioid therapy, should be placed in a lower Schedule separate from herbal cannabis, which should itself remain in Schedule I. In a 2005 letter to the United States Department of Health and Human Services,³³ that GW Pharmaceuticals distributes at public relations appearances, they boast of their UK license to cultivate various cannabis strains. This author has been told by an anonymous GW employee that the exclusive license was made possible because of Chairman Guy's personal relationship with former British Prime Minister John Major, who helped broker the company's exclusive deal with the Home Office. They argue that their lead product, proprietary name Sativex®, is "quite different" from "generic and unrefined cannabis" and that "it **cannot** be said that all cannabis—or all cannabis extracts—are

32. See <http://gwpharm.com/release-sativex-launch.aspx>.

33. See <http://www.oregon.gov/Pharmacy/Imports/Marijuana/StaffReview/NABP2009Symposium.pdf>, pp. 16-19.

the same.”³⁴ Finally, not wanting natural cannabis to share in any of their predicted future legitimization of their extract, they end by saying that “it would be a great irony if generic herbal cannabis were to be removed from Schedule I of the Controlled Substances Act, and made available for general medical use, based in part on data relating to a specific product [Sativex®].” Is not the real irony that GW would have the plant on which their entire company is based, relegated to the status of irredeemably dangerous drug, while their extract of the plant is blithely elevated to the status of profitable, salable good?³⁵ Is that any way to thank Mother Nature?

NABIXIMOLS OR HASH OIL?

One need only study the basic details of GW’s original process patent filed in 2002, and issued by the U.S. Patent and Trademark Office in 2008,³⁶ to see how their product is nothing more than a highly characterized, twenty-first century version of hash oil—with peppermint flavoring. Their patent application describes the “production of a relatively simple extract containing, as well as cannabinoids, only a limited number of non-target compounds, many of which can be removed relatively easily in a simple step.” Their production process consists of three basic steps: heating, extraction, and winterization. They start with homegrown cured and dried cannabis flowers taken from plants “propagated from cuttings taken from the mother plants, originating from a single seed source.” The flowers are finely milled into two to three millimeter-sized pieces and heated for fifteen minutes at 105 degrees Celsius and forty five minutes at 140 degrees Celsius in order to decarboxylate, or activate, the phytocannabinoids. Next, the activated plant matter is placed in a vat of liquid carbon dioxide held at a pressure of sixty barr³⁷ and ten degrees Celsius for eight hours. These temperature/pressure settings are technically below the supercritical fluid point of carbon dioxide (subcritical), but this method is generally referred to as supercritical fluid extraction, and it has the benefit of cleanly dissolving essentially every compound in the whole plant matter. This concept of extracting plant matter in liquid carbon dioxide was pioneered in 1822 by Baron Cagniard de la Tour, duly acknowledged in the patent, and a demonstration of such conditions can be achieved by placing dry ice in a corked test tube. In the final step, winterization, inert waxy material in the extract are precipitated out with a cold ethanol wash and filtered out. Once the ethanol is added, the mix-

34. *Id.* (emphasis in original).

35. GW obtained cannabis germplasms from Dutch seedbanks that had gathered diverse strain collections from around the world that had been bred, crossbred, and propagated over the ages.

36. U.S. Patent No. 7,344,736 (filed Mar. 18, 2008), available http://www.google.com/patents/download/7344736_Extraction_of_pharmaceutically_a.pdf?id=1N2oAAAAEBAJ&output=pdf&sig=ACfU3U0toN40EOzWpm-Gotsc81_6oZOd_Q.

37. Sixty barr is approximately sixty times greater than normal atmospheric pressure.

ture is cooled to negative twenty degrees Celsius and held at this temperature for approximately forty eight hours. The waxy precipitate is removed by filtration through a twenty μm membrane (which, for perspective, is approximately 100 times the pore-size of a household HEPA vacuum filter) and passed through activated charcoal (which helps to preserve shelf-life). Finally, the extract is dissolved in propylene glycol, a clear, faintly sweet, viscous liquid. When this process is performed with cannabis derived from two different strains, one with high THC (tetrahydrocannabinol) content and the other with high CBD (cannabidiol) content, and the two extracts are mixed together in a one to one ratio and a bit of peppermint flavor is added, voilà, Sativex® is created.

What is ultra-modern here is the highly characterized nature of the extract and optimized and quality-controlled conditions of its production; however, the basic principles of the process are not new. GW's patent itself refers on several occasions to cannabis as a medicinal plant and archeological evidence indeed suggests that the cultivation of cannabis for medicinal use stretches into pre-history. Taking varieties of dried plant material through the steps of heating for decarboxylation, extraction (usually in oil or alcohol), and even washing/winterization have been performed for centuries by various civilizations who have utilized cannabis preparations in ritual, medicine, and social custom. Nevertheless, the company was able to convince the WHO's International Non-proprietary Names and United States Applied Names programs that their cannabis extract, a 'botanical drug substance,' was deserving of a name other than "marijuana," "hash oil," or "cannabis," and thus it was granted the obfuscating name "nabiximols."³⁸ However, this substance is essentially hash oil. According to the DEA, "[t]he term hash oil is used by illicit drug users and dealers, but is a misnomer in suggesting any resemblance to hashish. Hash oil is produced by extracting the cannabinoids from plant material with a solvent."³⁹ Wikipedia even lists supercritical carbon dioxide as a potential solvent for hash oil production.⁴⁰ Were anyone else to produce this substance at a similar scale who lacks the social capital and insider connections of GW's executives, they could potentially face federal felony charges for marijuana production and be sentenced to death.⁴¹ For the everyday common person, marijuana is prohibited, and this definition of marijuana, first developed in 1937, is used:

38. See <http://www.ama-assn.org/ama1/pub/upload/mm/365/nabiximols.pdf>.

39. See http://www.justice.gov/dea/concern/hashish_oil.html.

40. See http://en.wikipedia.org/wiki/Hash_oil.

41. A death penalty is triggered in federal law at 60,000 marijuana plants or 60,000 kg of a mixture/substance containing a detectable quantity of marijuana. 18 U.S.C. § 3591(b) (2006) ("A defendant who has been found guilty of...an offense...which involved not less than twice the quantity of controlled substance described in subsection (b)(2)(A)...shall be sentenced to death.").

The term “marihuana” means all parts of the plant *Cannabis sativa* L., whether growing or not; the seeds thereof; the resin extracted from any part of such plant; and every compound, manufacture, salt, derivative, mixture, or preparation of such plant, its seeds or resin. Such term does not include the mature stalks of such plant, fiber produced from such stalks, oil or cake made from the seeds of such plant, any other compound, manufacture, salt, derivative, mixture, or preparation of such mature stalks (except the resin extracted therefrom), fiber, oil, or cake, or the sterilized seed of such plant which is incapable of germination.⁴²

There is nothing inherently amiss with cannabis-based pharmaceutical production, but the operation of such industry and its eventual product approval should not be allowed to exclude or impede general medicinal access to the class of organic botanicals from which such preparations are ultimately derived.

CONCLUSION: CANNABIS, CANNABINOIDS, AND THE FACTS OF LIFE

Despite the political hurdles, published, peer-reviewed scientific research on cannabis and cannabinoids has reached sizeable proportions. A 2009 review⁴³ found that there were over 15,000 articles published on the chemistry and pharmacology of cannabis and cannabinoids and over 2,000 on the endocannabinoid system. A 2010 review⁴⁴ counted at least 110 controlled clinical studies of cannabis or cannabinoids conducted around the world, mostly outside the U.S., involving over 6,100 patients with a wide range of conditions. The field is moving in multiple diverse directions as the homeostatic cannabinoid signaling system, thought to have evolved 600 million years ago, has been found to be intimately involved in areas such as tumor suppression, neuroprotection, antibiosis, and mood elevation--to name a few--in addition to its already well-accepted roles in pain, nausea, wasting, and muscle spasm mitigation. These newer indications are not fringe. One small pilot study in Spain showed radiographic evidence of shrinkage in brain tumor size with intra-tumoral injections of THC in humans⁴⁵ and the DHHS itself holds a

42. 21 U.S.C. § 802 (2006).

43. L.O. Hanuš, *Pharmacological and Therapeutic Secrets of Plant and Brain (Endo)Cannabinoids*, 29 *MEDICINAL RES. R.* 213-271 (2009).

44. Arno Hazekamp & Franjo Grotenhermen, *Review on Clinical Studies with Cannabis and Cannabinoids 2005-2009*, 5 *CANNABINOIDS* 1-21 (2010).

45. M. Guzmán, M.J. Duarte, C. Blázquez, J. Ravina, M.C. Rosa, I. Galve-Roperth, C. Sánchez, G. Velasco & L. González-Feria, *A Pilot Clinical Study of 9-Tetrahydrocannabinol in Patients with Recurrent Glioblastoma Multiforme*, 95 *BRIT. J. OF CANCER*, 197-203 (2006).

“novel application” patent⁴⁶ on the use cannabinoids as antioxidants and neuroprotectants.

At the center of all of this is a thirty seven million year old plant, Cannabis, the only known botanical to robustly produce a plethora of secondary metabolites now known as cannabinoids in its flowers’ resin. Should this plant be returned as a commons resource for local development and be subject to local regulation? Or should it be monopolized from afar by world governments and their pharmaceutical interest designees? Judged under the light of day, only one of these paths seems to be the sustainable one heading towards maximal health and social benefit.

46. U.S. Patent No. 6,630,507 (Oct. 7, 2003); *see also* <http://coloradoindependent.com/47995/feds-theres-no-medical-marijuana-except-our-medical-marijuana>.